

What is claimed is:

Sub 3

1. A method of increasing vertebrate muscle mass and muscle strength, said method comprising administering a muscle enhancing dose of an isolated nucleic acid encoding Insulin-like Growth Factor I (IGF-I), or a modification or biologically active portion thereof, intramuscularly into a vertebrate, wherein said isolated nucleic acid is expressed in muscle cells, thereby increasing said muscle mass and said muscle strength in the muscle of said vertebrate.

2. The method of claim 1, wherein said vertebrate is selected from a group consisting of rat, mouse, cat, dog, horse, cow, pig, sheep, goat, fish, bird, and human.

3. The method of claim 2, wherein said vertebrate is a human.

4. The method of claim 1, wherein said IGF-1 is of the same species as said vertebrate.

5. The method of claim 1, wherein said isolated nucleic acid is contained within a virus vector.

6. The method of claim 5, wherein said muscle enhancing dose ranges from between about 10^{10} to about 10^{12} recombinant virus vector particles per gram of muscle.

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7. An isolated nucleic acid comprising a vertebrate IGF-I coding region, or a modification or portion thereof, operably linked to a muscle specific promoter/regulatory region, wherein said IGF-I coding region is flanked on the 5' side

by an SV40 intron sequence and wherein said IGF-I coding region is flanked on the 3' end by an SV40 polyadenylation signal sequence.

5 8. The isolated nucleic acid of claim 7, wherein said muscle specific promoter/regulatory region is selected from a group consisting of the myosin light chain 1/3 promoter/enhancer, the skeletal α -actin promoter, the muscle creatine kinase promoter/enhancer and a muscle specific troponin promoter.

9. The method of claim 8, wherein said muscle specific troponin promoter is the fast troponin C promoter/enhancer.

10 10. The isolated nucleic acid of claim 8, wherein said muscle specific promoter/regulatory region is the myosin light chain 1/3 promoter/enhancer.

11. The isolated nucleic acid of claim 7, wherein said muscle specific promoter/regulatory region further comprises an enhancer element operably linked to the IGF-I coding region.

15 12. The isolated nucleic acid of claim 11, wherein said enhancer is the myosin light chain 1/3 enhancer.

13. A composition comprising a recombinant virus vector comprising said isolated nucleic acid of claim 12.

20 14. The composition of claim 13, wherein said recombinant virus vector is selected from the group consisting of an adeno-associated virus, an adenovirus and a herpes simplex virus.

15. The composition of claim 14, wherein said recombinant virus vector is an adeno-associated virus.

16. A cell comprising the isolated nucleic acid of claim 7.

17. A cell comprising the recombinant virus vector of claim 15.

5 18. A kit for increasing muscle mass and muscle strength in a vertebrate, said kit comprising a muscle enhancing dose of the isolated nucleic acid encoding IGF-I of claim 7, wherein said isolated nucleic acid is expressed in vertebrate muscle cells, and wherein said kit further comprises an applicator for delivering said muscle enhancing dose, and instructions for the use of said kit.

10 19. A non-human transgenic vertebrate animal comprising an isolated nucleic acid encoding Insulin-like Growth Factor I (IGF-I), or a modification or biologically active portion thereof.

15 20. The non-human transgenic vertebrate animal of claim 19, wherein said IGF-1 is operably linked to a muscle specific promoter/regulatory sequence at the 5' end of said IGF-1 and a polyadenylation termination signal at the 3' end of said IGF-1.

20 21. The non-human transgenic vertebrate animal of claim 20, wherein said muscle specific promoter/regulatory sequence is selected from the group consisting of the myosin light chain 1/3 promoter/enhancer, the skeletal α -actin promoter, the muscle creatine kinase promoter/enhancer and a muscle specific troponin promoter.

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